PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Health Literacy in Italy—A cross-sectional study protocol to assess the health literacy level in a population-based sample, and to validate health literacy measures in the Italian language
AUTHORS	Lorini, Chiara; Santomauro, Francesca; Grazzini, Maddalena; Mantwill, Sarah; Vettori, Virginia; Lastrucci, Vieri; Bechini, Angela; Boccalini, Sara; Bussotti, Alessandro; Bonaccorsi, Guglielmo

VERSION 1 – REVIEW

REVIEWER	Orkan Okan Bielefeld University, Faculty of Educational Science, AG 2 Socialisation, Centre for Prevention and Intervention in Childhood and Adolescence (CPI), Bielefeld, Germany
REVIEW RETURNED	04-Jun-2017

GENERAL COMMENTS	Your protocol/study report describes every important step of your study and you clearly outline the problem as well as your strategy how you are going to apply the results. Health literacy is still an evolving field of research and indeed is very important in both health promotion and healthcare research. This study report and the results of your study addressing health literacy in Italy, where to this date only very few empirical studies have been conducted, will significantly add to the evidence base in this field and the whole health literacy arena will benefit from it once you have finished data collection and analysis in September 2017. Especially the fact that you address both related antecedents and outcomes is an aspect that makes your study very important as a) not much is known about this connection and b) there have been many scholars calling for such approaches in health literacy research in the recent past. This protocol will not only ensure transparency of your study but will also allow others to learn from your design and approach. The background is clearly reflecting upon the state of the art in your field of study and it has many relevant, appropriate, and up-to-date references allowing comparison with other papers and studies. This section is clearly defining your research questions and aims of your manuscript. However, there is one paper published by Reeve and Basalik (2014), which is criticising the NVS and similar measurement tools regarding their underlying health literacy construct, which they argue to be the literacy construct, and for literacy, they highlight, there are much better and better validated tools. It might improve the quality of your paper to also reflect upon critical perspectives existing towards the NVS, but, of course, this is not necessarily required.

	The study design, population and sample criteria, data collection procedures as well as the measurement tools, including the tables with detailed information and the questionnaire items in both English and Italian, and outcome variables are well described and they leave no questions open. The planned statistical analyses are well described against the study objectives 1-4. Reporting on ethical issues and the provision of the dissemination strategy are appropriately described. General: You could use some additional keywords related to your study. Page 2, Line 44: “Many tools exist to measure HL but until this date none of them is considered to be the gold standard.” This sentence needs one of the references that you are using below, see Line 53. Please make sure to always use the same form of a word, i.e. page 3, Line 55 “healthcare” vs. page 4, Line 45 “health care”.

REVIEWER	Professor Jürgen Pelikan Austrian Public Health Institute and University of Vienna, Vienna / Austria
REVIEW RETURNED	08-Jun-2017

GENERAL COMMENTS	A very ambitious well planned study, my concerns and suggestions are: Concerns: The study has a very well planned combination of convenience and probability sampling, but due to telephone interviews considerable dropouts and distortions of the sample have to be expected. Hopefully the involvement of the GPs and the first contact by postal mail will mitigate this. Usually the NVS test is done in face to face interviews, but in this study it is planned for telephone interviews, it is interesting how well this will work! The NVS Test, definitely is the most multi-dimensional of the available HL short tests, but its scope concerning the content and meaning of HL still is much narrower than e.g. that of the HLS-EU-Q. This has to be taken into account when NVS is used as the yard stick for measuring HL! Concerning the translation of the HLS-EU-Q16 into Italian, there already is a translation of the whole HLS-EU-Q47 into Italian by Palumbo et al 2016. From the article it is not clear, if there was a separate translation into Italian for the HLS-EU-Q16 by this study and in how far it has been harmonized with the Palumbo et al. translation. May be overall a stronger cooperation with the Palumbo group might be of advantage for the planned study! Suggestions: Since the HLS-EU-Q16 has been developed from the HLS-EU-Q47 by using Rasch Analysis and has been demonstrated for many countries to show Rasch scalability it would be interesting to do this kind of analysis also in the planned study! Concerning indicators for antecedents and consequences of HL, no indicators have been chosen for health behaviors or risk factors, like physical activity, BMI, alcohol or tobacco use,

	for which have been shown interesting associations with HL in other studies. On the other side for antecedents have been included indicators like marital status or number of family members, where there is neither theoretical or empirical strong evidence for association. Maybe some less indicators for antecedents and some more for consequences might be preferable.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Orkan Okan
Institution and Country: Bielefeld University, Faculty of Educational Science, AG 2 Socialisation, Centre for Prevention and Intervention in Childhood and Adolescence (CPI), Bielefeld, Germany
Competing Interests: None declared.

Comment: The background is clearly reflecting upon the state of the art in your field of study and it has many relevant, appropriate, and up-to-date references allowing comparison with other papers and studies. This section is clearly defining your research questions and aims of your manuscript. However, there is one paper published by Reeve and Basalik (2014), which is criticising the NVS and similar measurement tools regarding their underlying health literacy construct, which they argue to be the literacy construct, and for literacy, they highlight, there are much better and better validated tools. It might improve the quality of your paper to also reflect upon critical perspectives existing towards the NVS, but, of course, this is not necessarily required.

Response: Thank you for suggesting reading the paper by Reeve and Basalik. Concerns about NVS and other tools primarily designed to detect illiteracy has been added, as well as suggestions to control for it:
“Anyway, as noted by Reeve and Basalik52, HL tests were primarily designed to detect illiteracy, so they often show ceiling effect when used in the general population. Ceiling effect can significantly skew distribution, and leads to concern about attenuated correlation. In our study, this phenomenon could be observed for NVS-IT, BHLS, and two subjective numeracy items, while the HLS-EU-Q47 and its short forms have initially been validated in the general population. Possible ceiling effect and skewed distribution will be considered in the statistical analysis.”

General:
You could use some additional keywords related to your study.
Rep.: Additional keywords have been added

Comment: Page 2, Line 44: “Many tools exist to measure HL but until this date none of them is considered to be the gold standard.” This sentence needs one of the references that you are using below, see Line 53.
Response: References have been added

Comment: Please make sure to always use the same form of a word, i.e. page 3, Line 55 “healthcare” vs. page 4, Line 45 “health care”.

Response: The text has been proofread

Reviewer: 2
Reviewer Name: Professor Jürgen Pelikan
Institution and Country: Austrian Public Health Institute and University of Vienna, Vienna / Austria
Competing Interests: None declared

Comment: A very ambitious well planned study, my concerns and suggestions are:
Concerns:
The study has a very well planned combination of convenience and probability sampling, but due to telephone interviews considerable dropouts and distortions of the sample have to be expected. Hopefully the involvement of the GPs and the first contact by postal mail will mitigate this.
Usually the NVS test is done in face to face interviews, but in this study it is planned for telephone interviews, it is interesting how well this will work!
The NVS Test, definitely is the most multi-dimensional of the available HL short tests, but its scope concerning the content and meaning of HL still is much narrower than e.g. that of the HLS-EU-Q. This has to be taken into account when NVS is used as the yard stick for measuring HL!

Response.: Thank you for your suggestions! We will take into account them when we will discuss the results

Comment: Concerning the translation of the HLS-EU-Q16 into Italian, there already is a translation of the whole HLS-EU-Q47 into Italian by Palumbo et al 2016. From the article it is not clear, if there was a separate translation into Italian for the HLS-EU-Q16 by this study and in how far it has been harmonized with the Palumbo et al. translation.
May be overall a stronger cooperation with the Palumbo group might be of advantage for the planned study!

Response: We have read the paper of Palumbo et al. (2016) aimed in investigating HL in a sample of Italian citizen using the HL-EU-Q47. Unfortunately, the paper does not contain the Italian version of the HL-EU-Q47 they have used, so, when we were designing our study, we have contacted Palumbo in order to use their translated version. Palumbo responded to our mail, specifying that he would send us their version of the questionnaire, but he never did it. Therefore, we have decided to start our study making our translation. Maybe we will meet Palumbo and his group next November during a residential course, and we might be able to compare the two translations.

Comment:
Since the HLS-EU-Q16 has been developed from the HLS-EU-Q47 by using Rasch Analysis and has been demonstrated for many countries, to show Rasch scalability it would be interesting to do this kind of analysis also in the planned study!

Response: Rash analysis has been added in the “Statistical analysis” section:
“Since the HLS-EU-Q16 was developed from the HLS-EU-Q47 using Rash analysis43, this analysis will be performed on the Italian version of the HLS-EU-Q16 to describe the ‘test-item difficulty’, its strengths, and its weaknesses.51”

Comment: Concerning indicators for antecedents and consequences of HL, no indicators have been chosen for health behaviors or risk factors, like physical activity, BMI, alcohol or tobacco use, for which have been shown interesting associations with HL in other studies. On the other side for antecedents have been included indicators like marital status or number of family members, where there is neither theoretical or empirical strong evidence for association. Maybe some less indicators for antecedents and some more for consequences might be preferable.

Response: As regards to indicators for risk factors, BMI will be considered as health outcome since weight and height are requested (see " Health outcome variables" sector). Other indicators of health behaviours or risk factors were not included in the questionnaire not to lengthen the interview times. Anyway, since the Italian surveillance system PASSI collects many health behavior or risk factor indicators, statistical analysis aimed in assessing the relationship between HL and those indicators will be performed when the HL-EU-Q6 will be included in the surveillance (I hope next year). Concerning antecedents, marital status and number of family members were included in the questionnaire since in an our previous research conducted in Lagonegro (Potenza, Italy) they resulted significantly associated with HL. The paper with the results of our study conducted in Lagonegro is in press on Annali dell'ISS.

VERSION 2 – REVIEW

REVIEWER	Professor Jürgen Pelikan Austrian Public Health Institute and University of Vienna / Austria
REVIEW RETURNED	11-Aug-2017

GENERAL COMMENTS	Doing the NVS by telephone interviews, requires some comment! It should be made clear in how far the translation of the HLS-EU-Q16 into Italian by this research team agrees with the translation of the HLS-EU-Q47 into Italian by Palumbo et al. 2016!

VERSION 2 – AUTHOR RESPONSE

Reviewer: 2
Reviewer Name: Professor Jürgen Pelikan
Institution and Country: Austrian Public Health Institute and University of Vienna / Austria Competing Interests: None declared

Comment: Doing the NVS by telephone interviews, requires some comment!

Response: Comments on the methods of administration of NVS have been added both in the methods section and in the discussion section. Specifically, in the methods: "Moreover, it was originally developed to be administered by face-to-face interviews, although in one study a web-based survey was conducted29 and in another it was self-administered.32 To the best or our knowledge, no published studies have reported NVS data collected through telephonic interviews."
In the discussion: "In this study, telephone interviews are used to collect NVS-IT data, while in almost all the studies face-to-face interviews are used. To date, no data have been published concerning the comparison of NVS data collected using different methods of administration. Compared to face-to-face interviews, telephone interviews offer several advantages45, namely, the elimination of any bias caused by the appearance of the interviewer, lower costs related to the transfers of the interviewer or the person interviewed, and lower administrative costs. Moreover, there is some evidence that people are more likely to report health-related events on the phone rather than in face-to-face interviews.45 The potential problems with telephone interviewing are instead as follows: the respondent may seek help from another person at home, and there is no assurance who the person is at the other end on the line. This second risk is difficult to completely eliminate, while the first one is minor45 since the interviewer would be able to notice the involvement of other people (i.e. the person on the phone would have to repeat each question or use the hands-free mode)."

It should be made clear in how far the translation of the HLS-EU-Q16 into Italian by this research team agrees with the translation of the HLS-EU-Q47 into Italian by Palumbo et al. 2016!
I am sorry but, regretfully, I cannot describe the differences in the translation of the HLS-EU-Q16 since the version of Palumbo et al. is not available neither on the published article nor on the internet, and, in spite of our request, Palumbo has not send us his translation of HLS-EU-Q16. In summary: I am unable to consult the Palumbo version.